IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 112280.121US3

Applicants:	Opolski, M.	)	Examiner:	Reddick, J.
		)		
Filed:	May 15, 2001	)	Art Unit:	1713
		)		
Serial No.:	09/855,923	)		
		)		
Entitled:	Water-Based Hydrophilic Compositions and Articles Prepared Therefrom	)		

CERTIFICATION UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450 on the date indicated below.

11/19/03
Date of Signature and of Mail Deposit

Janet McKean

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Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

DECLARATION OF MARGARET P. OPOLSKI UNDER 37 CFR §1.132

Under 37 CFR §1.132 and regarding the rejection of the pending claims over U.S. Patent 5,478,872 ("the Yamasoe patent"), I declare:

1. I am an inventor of the subject matter described and claimed in the above-captioned patent application.

2. I have been working in the field of polymer coatings and adhesives for 28 years and in particular their use with medical devices for at least 15 years. My *curriculum vitae* is attached as Exhibit 1.

3. I have read and understood the office action dated August 13, 2003. The Examiner asserted "the functional moiety of the acrylic polymer per Yamasoe et al. has an equivalent

weight falling within the scope of the claims. It would be expected that the crosslink density of the acrylic polymer system of Yamasoe et al. is sufficient to engender a slip retention of the hydrophilic coating falling within the scope of the claims since the hydrophilic coating of Yamasoe *et al.* is essentially the same as and made in essentially the same manner as applicant's claimed hydrophilic coating. The onus to show that this, in fact, is not the case is shifted to applicant..." This Declaration is made to provide information regarding the equivalent weights of the polyacrylate systems disclosed in the Yamasoe patent.

4. In general, the equivalent weight ("EW") of a polymer is the weight of polymer component per functional group. For a simple homopolymer, the equivalent weight can be calculated by taking the molecular weight of the monomeric unit of the polymer and dividing it by the number of the functional moieties per monomeric unit.

5. If a polymer is made up of more than one type of monomeric unit or is a polymer blend (as found in the Yamasoe patent), the weighted contribution of each monomeric unit or blend component to the equivalent weight of the total polymer composition is determined. The weighted contribution is determined by multiplying the equivalent weight of each monomeric unit or blend component by its weight fraction in the total polymer composition.

6. The Examiner has identified the Yamasoe patent and, in particular, examples 8, 31, 37-44, and 77-102 as relevant to my invention. These examples disclose polymer compositions including polyethylene oxide (MW 500,000) and/or polyvinyl pyrrolidone (PVP) as the hydrophilic polymer(s) and an aqueous resin including some or all of the following components: γ-polyglutamic acid (PGA, MW 300,000), carboxymethyl cellulose (CMC, MW 20,000), N-methylol acrylamide, and polyacrylic acid (PAA, MW 100,000). After polymerization, the resulting supporting polymer is a polyacrylate polymer blend. Examples 37-44 and 77-102 use either H_2ZrF_6 or $(NH_4)_3ZrOH(CO_3).2H_20$ as a cationic crosslinking agent. I have consulted with Larry Cohen, owner and chemist for Chartwell International (a supplier of zirconium compounds), and determined that zirconium salts react with functional moieties having an active hydrogen, such as hydroxyl and carboxylic acid sites. This information was used to determine the equivalent weights of the polymer blends of Examples 8, 31, 37-44 and 77-102.

7. *N*-Methylol acrylamide has a molecular weight of 101 and one free hydroxyl moiety ("functional moiety") available for crosslinking, and therefore its equivalent weight is 101. The monomeric unit for γ-PGA (glutamic acid) has a molecular weight of 147 and one free carboxylic acid moiety ("functional moiety"), available for crosslinking, and therefore γ-PGA has an equivalent weight of 147. The monomeric unit for PAA (acrylic acid) has a molecular weight of 72 and one free carboxylic acid moiety ("functional moiety") available for crosslinking, and therefore PAA has an equivalent weight of 72. Lastly, the monomeric unit for CMC has four hydroxyl and two carboxylic acid moieties ("functional moieties") available for crosslinking per repeating unit and a molecular weight of 447. It follows therefore CMC has an equivalent weight of 75. The weighted contribution of each polymer component is determined using the following relationship:

$$EW_{polymer} = EW_{monomer} \cdot weight_{monomer} / \text{total polymer weight}$$

Using the above relationship, the equivalent weights of the cited examples were calculated and are reported in the following tables.

EXAMPLES 37 - 44

Example	γ-PGA	CMC	NMA (acrylic monomer)	PAA	EW
37	42	21.4	28.9	10.3	102.6
38	17.3	26.5	35.7	12.7	92.2
39	58.8	18.0	24.24	8.64	109.7
40	47.42	24.2	32.6	2.32	106.54
41	36.75	18.75	25.25	18.00	98.75
42	51.8	8.82	35.65	12.71	109.06
43	35.28	30.00	24.24	8.64	98.16
44	0	26.79	36.07	20.57	83.43

EXAMPLES 77 - 102

Example	CMC-Na	CMC-Ka	CMC-NH_4	NMA (acrylic monomer)	PAA	EW
77	7.50	0	22.5	40.4	14.4	84.08
78	7.50	0	22.5	40.4	14.4	84.08
79	7.50	0	22.5	40.4	14.4	84.08
80	7.50	0	22.5	40.4	14.4	84.08
81	7.50	0	22.5	40.4	14.4	84.08
82	3.00	0	15.0	56.56	14.4	88.96
83	3.00	0	15.0	56.56	14.4	88.96
84	15.0	0	30.0	20.2	14.4	79.60
85	3.0	0	30.0	36.36	14.4	83.76
86	0	7.5	22.5	40.4	14.4	84.80
87	7.5	0	22.5	40.4	14.4	84.80
88	7.5	0	22.5	40.4	14.4	84.80
89	7.5	0	22.5	40.4	14.4	84.80
90	7.5	0	22.5	40.4	14.4	84.80
91	7.5	0	22.5	40.4	14.4	84.80
92	7.5	0	22.5	40.4	14.4	84.80
93	7.5	0	22.5	40.4	14.4	84.80
94	6.25	0	18.75	33.67	24.00	82.67
95	9.38	0	28.13	50.5	0	88.01
96	7.5	0	22.5	40.4	14.4	84.8
97	0	6.25	18.75	33.67	24.00	82.67
98	7.5	0	22.5	40.4	14.4	84.8
99	7.5	0	22.5	40.4	14.4	84.80
100	7.5	0	22.5	40.4	14.4	84.8
101	0	7.5	22.5	40.4	14.4	84.8
102	6.82	6.82	20.45	36.73	13.09	83.91

9. Composition (Run) 8 does not describe exact gram amounts of the aqueous resin employed. Rather, for each monomeric unit a possible range is given. Therefore, the exact equivalent weight for the total polymer composition can not be calculated. However, the equivalent weights of each of the monomers, oligomers, and polymers used by Yamasoe are less than 200. Therefore, no combination of such monomeric units will ever produce a supporting polymer having an equivalent weight of greater than 200.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patents issued thereon.

Date: 11/17/03

Margaret Palmer Opolski
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